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IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA,
EASTERN DIVISION

JENNIE FRERE, Plaintiff, vs. MEDTRONIC, INC.; MEDTRONIC NEUROMODULATION, a division of MEDTRONIC, INC.; MEDTRONIC PUERTO RICO OPERATIONS CO.; MEDTRONIC USA, INC., and MEDTRONIC LOGISTICS, LLC, Defendants.	Case No. 5:15-cv-02338-BRO(DTBx) **NOTICE OF MOTION TO DISMISS** Date: June 6, 2016 Time: 1:30 p.m. Judge: Beverly Reid O'Connell [Filed Concurrently with Motion to Dismiss; Exhibits A-K; Proposed Order]

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

NOTICE IS HEREBY GIVEN that on Monday, June 6, 2016 at 1:30 p.m., or as soon thereafter as counsel may be heard by the Honorable Beverly Reid O'Connell, Defendants Medtronic, Inc., Medtronic Puerto Rico Operation Co., Medtronic USA, Inc., and Medtronic Logistics, LLC (together "Medtronic") will

move the Court for an order dismissing Plaintiff's First Amended Complaint with prejudice on the ground that Plaintiff's claims are expressly preempted by the Medical Device Amendments Act of 1976, 21 U.S.C. § 360(c), *et seq.*, the Federal Food Drug & Cosmetic Act, 21 U.S.C. § 301, *et seq.*, and the regulations promulgated pursuant to those Acts, and because there is no private right of action under the Federal Food, Drug & Cosmetic Act or the Medical Device Amendments thereto. *See* 21 U.S.C. § 337. Further, Plaintiff's claims are inadequately pled and subject to dismissal on independent state law grounds.

Medtronic's Motion to Dismiss is submitted with this Notice of Motion, Exhibits A – K, and a Proposed Order. The Motion is made following conferences of counsel pursuant to L.R. 7-3, which took place on February 1, February 2, and February 4, 2016.

Dated: February 8, 2016

MEDTRONIC, INC.

By: /s/ Julie Cantor

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JENNIE FRERE, Plaintiff, vs. MEDTRONIC, INC.; MEDTRONIC NEUROMODULATION, a division of MEDTRONIC, INC.; MEDTRONIC PUERTO RICO OPERATIONS CO.; MEDTRONIC USA, INC., and MEDTRONIC LOGISTICS, LLC, Defendants.	Case No. 5:15-cv-02338-BRO(DTBx) **DEFENDANTS' RULE 12(b)(6) MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT** Date: June 6, 2016 Time: 1:30 p.m. Judge: Beverly Reid O'Connell [Filed Concurrently with Notice of Motion; Exhibits A-K; Proposed Order]

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In this lawsuit, Plaintiff asserts products liability claims against Defendants (together "Medtronic")[1] under California and Minnesota law. *See* First Amended Complaint (Dkt. # 10) ("Complaint" or "FAC"). Plaintiff alleges injuries caused by a failure of her InDura 1P Model 8709SC Intrathecal Catheter, a Class III prescription, implanted medical device that is part of and used in conjunction with the SynchroMed® II Programmable Drug Infusion System (the "SynchroMed® II Infusion System"). The SynchroMed® II Infusion System is a Class III medical device that treats certain medical conditions by delivering medication (i.e., morphine sulfate or baclofen) via an implanted pump and catheter directly to the "intrathecal" area where fluid flows around the spinal cord.

The Food and Drug Administration ("FDA") has approved the SynchroMed® II Infusion System under its Premarket Approval ("PMA") process, its most rigorous standard for medical devices. Given this fact, Plaintiff's claims are expressly preempted under 21 U.S.C. § 360k(a) (to the extent they are based on state law) and impliedly preempted under 21 U.S.C. § 337(a) (to the extent they are attempting to enforce federal regulations governing the device).

Plaintiff's claims are subject to dismissal on other grounds. Namely: (1) she has not plausibly alleged facts supporting key claim elements; (2) she has not pled her fraud claims with the detail Rule 9(b) requires; (3) her claims are time-barred; and (4) California law precludes her Unfair Competition Law ("UCL") claim.

BACKGROUND

The FDA strictly regulates the design, manufacture, and sale of Class III medical devices pursuant to the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"). The following sections summarize this regulatory regime and its relationship to Plaintiff's claims.

[1] Plaintiff named "Medtronic Neuromodulation" as a Defendant, but Medtronic Neuromodulation is a division of Medtronic, Inc. and not a separate legal entity.

A. The Rigorous Premarket Approval Process.

The Medical Device Amendments "swept back some state obligations and imposed a regime of detailed federal oversight" on medical device manufacturers. *Riegel v. Medtronic Inc.* 552 U.S. 312, 316 (2008). The Medical Device Amendments create different levels of federal oversight, depending on the risks associated with a device. Class III devices like the SynchroMed® II Infusion System are those which are used "in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or which "present[] a potential unreasonable risk of illness or injury." *Id.* at 317 (quoting 21 U.S.C. § 360c(a)(1)). Class III devices that are submitted for premarket approval by the FDA receive the greatest scrutiny before they are sent to market.

"Premarket approval is a 'rigorous' process." *Id.* (citation omitted). It requires manufacturers to submit detailed information regarding the proposed design, manufacture, and labeling of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission. *Id.* at 317-18. After conducting a thorough cost-benefit analysis, the FDA "grants premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Id.* at 318 (citing 21 U.S.C. § 360e(d)). If the FDA grants approval, the manufacturer may not "make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319 (citing § 360e(d)(6)(A)(i)).

The FDA's oversight of PMA devices continues after approval through monitoring and regulation of product manufacture, labeling, marketing, and design changes affecting safety or efficacy. *Id.* at 319. Further, federal regulations prohibit the production or labeling of any device in a manner inconsistent with any conditions of approval set by the FDA. 21 C.F.R. § 814.80. The applicant must also submit a supplemental application for FDA approval setting forth any proposed changes affecting safety and effectiveness. 21 C.F.R. § 814.39.

In short, through the PMA process, the FDA engages in a thorough and ongoing analysis that weighs the potential benefits of a device against its potential risks. Via PMA review, the FDA has final and exclusive authority over the regulation of a PMA Class III device. To maintain this exclusive authority, the Medical Device Amendments contain an express preemption provision declaring that no state "may establish or continue in effect with respect to a device . . . any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a). Thus, state-law claims challenging the design, manufacture, or labeling of a PMA medical device are expressly preempted. *Riegel*, 552 U.S. at 321-25. Although the Supreme Court noted that preemption leaves some injured individuals without judicial recourse, the Court found that this is required by § 360k(a) and is justified because, absent preemption, many more individuals "would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations." *Id*. at 326.

The FDCA also contains a "no private right of action" clause stating that all actions to enforce its requirements "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Thus, the FDA – not private citizens – has the authority to investigate violations of the FDCA, its amendments, and regulations promulgated thereunder, and "has at its disposal a variety of enforcement options that allow it to make a measured response" to wrongdoing it uncovers. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 (2001).

B. Plaintiff's SynchroMed® II Infusion System Received FDA Approval through the Rigorous PMA Process.

Plaintiff admits that the SynchroMed® II Infusion System is a Class III, PMA medical device. (FAC ¶¶ 55; *see* Ex. A (SynchroMed® II Premarket Approval Database Listing for P860004/S056) at 1.) The FDA granted premarket

approval to the original SynchroMed® Pump & Infusion System in 1988 (*see* Ex. B (SynchroMed® Premarket Approval Database Listing) at 1)[2], and has since approved numerous supplements, which are the manufacturer's proposed changes to the original device. (*See id.*)[3] Plaintiff's Model 8637-20 pump received PMA approval via Supplement 56 on September 12, 2003. (FAC ¶ 13; Ex. A at 1.)

The specific device component at issue in this case, Plaintiff's Model 8709SC catheter (FAC ¶ 13), is also premarket approved. The original Model 8709 catheter was approved via Supplement 39 on May 21, 1998. (Ex. C at 1.) Subsequently, on March 22, 2006, the FDA approved the version at issue here, the Model 8709SC Catheter – a "sutureless connector" version of Model 8709 – via Supplement 81. (Ex. D (SynchroMed® II Premarket Approval Database Listing for P860004/S081) at 1; Ex. E (FDA approval letter) at 1.) In short, there can be no dispute that Plaintiff's SynchroMed® II Infusion System and all of its components comprise a Class III, PMA medical device.

The FDA's oversight did not end upon premarket approval of the original device or the subsequent supplements. Rather, the SynchroMed® II Infusion System continues to be subject to rigorous FDA oversight. *E.g.*, 21 C.F.R. §§ 814.39(a), 814.82, 814.84. If the FDA concludes that Medtronic is not complying

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[2] The Court may take judicial notice of the FDA's PMA documents because they are government records that are not subject to reasonable dispute. *See* Fed. R. Evid. 201(b). In concluding that Class III devices have received PMA approval, courts across the country have taken judicial notice of documentation similar to that submitted with this Motion by Medtronic. *E.g.*, *McBride v. Medtronic, Inc.*, No. 13-377, 2013 WL 3491085, at *2 (W.D. La. July 10, 2013); *Erickson v. Boston Scientific Corp*. 846 F. Supp. 2d 1085, 1089 (C.D. Cal. 2011); *Heisner ex rel. Heisner v. Genzyme Corp.*, No. 08-C-593, 2008 WL 2940811, at *1 (N.D. Ill. July 25, 2008).

[3] The approval listings cited herein are accessible via the FDA's searchable database at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. The FDA does not issue static web addresses for these kinds of documents, so they can be reliably obtained only from this searchable FDA database.

with PMA requirements, the FDA can, and has the exclusive authority to, enforce its requirements. *See* 21 U.S.C. §§ 337(a), 351, 352, 360h, 374.

C. Plaintiff's Claims against Medtronic.

Plaintiff allegedly suffers from lumbar post-laminectomy syndrome and chronic lower back pain. (FAC ¶ 19.) Prior to receiving her SynchroMed® II Infusion System, she received numerous treatments to manage her severe and chronic pain, including a spinal cord stimulator, lumbar steroid injections, lumbar facet block, pedicle screws, and back fusion. These treatments all failed to provide lasting relief. (*Id.*) In January 2009, Plaintiff underwent trial therapy with the SynchroMed® II Infusion System that reduced her pain by 80 percent. (*Id.* ¶ 20.) On February 5, 2009, Plaintiff's physicians implanted the SynchroMed® II Infusion System into her body.[4] (*Id.*)

"Shortly after" the February 2009 implantation, Plaintiff allegedly began to "suffer complications" from her device that purportedly led to continuing pain. (*Id.* ¶ 21.) On December 22, 2011, after allegedly determining that "medication was not being delivered to [Plaintiff's] intrathecal space," Plaintiff's physician performed a revision surgery and "re-implant[ed]" her device. (*Id.* ¶¶ 22-23.) Despite this, her pain continued for years. (*Id.* ¶ 23.) On January 23, 2014, Plaintiff's physician performed another revision surgery and "explanted the malfunctioning pump." (*Id.* ¶ 24.) During the procedure, the physician allegedly noticed that the catheter implanted in 2009 had fractured and a fragment of its distal end was missing. (*Id.*)

Several weeks later, on March 8, 2014, Plaintiff was admitted to the emergency room for a suspected infection near the site of her previously implanted

[4] The Complaint contains conflicting references to Plaintiff's catheter as Model 8709 or Model 8709SC. (*Compare, e.g.* FAC ¶ 20 *with id.* ¶ 34.) Medtronic's records reflect that Plaintiff received a Model 8709SC catheter. For purposes of this Motion, however, the distinction is immaterial because both catheters are and have always been PMA devices. (Exs. C-E.)

pump and catheter. (*Id.* ¶ 28.) Plaintiff again underwent surgery, and her physicians located and removed the distal catheter fragment. (*Id.* ¶ 29.) The physicians also identified signs of infection in Plaintiff's spinal fluid and the pump pocket. (*Id.*) Plaintiff received IV antibiotics for 6 weeks, but her IV line became infected and she was readmitted for further treatment in late April 2014. (*Id.* ¶ 30.)

On April 22, 2015, approximately six years after she allegedly began suffering complications, Plaintiff filed her original complaint. After removing the case to federal court on November 13, 2015 (Dkt. # 1), Medtronic moved to dismiss the original complaint based on preemption and state-law defenses. (Dkt. # 7.) Subsequently, the parties filed and the Court entered a Stipulation and Order permitting Plaintiff to file an amended complaint (Dkt. ## 8-9), which Plaintiff did on December 23, 2015. (Dkt. # 10.) Plaintiff now asserts the following claims: (1) strict liability – manufacturing defect; (2) strict liability – failure to warn; (3) breach of express warranty; (4) breach of implied warranty; (5) fraud; (6) negligent failure to instruct and train medical providers; (7) violation of California's UCL; and (8) violation of Minnesota consumer protection statutes. Medtronic now moves to dismiss the First Amended Complaint.

LEGAL STANDARD

To survive a motion to dismiss under Rule 12(b)(6), Plaintiff's Complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Although the Court must accept Plaintiff's well-pleaded factual allegations as true, "naked assertion[s] devoid of further factual enhancement" will not suffice. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation marks omitted); *see also Twombly*, 550 U.S. at 563 n.8 ("[B]efore proceeding to discovery, a complaint must allege facts suggestive of illegal conduct."). Dismissal is required "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct," *Iqbal*, 556 U.S. at 679, and also where the factual allegations are "so sketchy that the

complaint does not provide the type of notice of the claim to which the defendant is entitled under Rule 8." *Villegas v. J.P. Morgan Chase & Co.*, No. C 09-00261 SBA, 2009 WL 605833, at *3 (N.D. Cal. Mar. 9, 2009) (quotation marks omitted).

ARGUMENTS AND AUTHORITIES

As detailed below, Plaintiff's claims against Medtronic are expressly and impliedly preempted (Parts I and II below). Even setting aside preemption, Plaintiff's claims are inadequately pleaded (Part III below) and subject to dismissal on independent state-law grounds (Part IV below).

The Medical Device Amendments to the FDCA create an exclusive federal regulatory framework for ensuring the safety and effectiveness of Class III PMA medical devices that is administered and enforced by the FDA. *Riegel*, 552 U.S. 312. In *Riegel*, the Supreme Court held that 21 U.S.C. § 360k(a) prohibits states from imposing any safety or effectiveness standard (including any state common-law standard) on a PMA device that is different from or in addition to those which the federal government imposes. Further, in *Buckman*, 531 U.S. at 348-49, the Supreme Court held that 21 U.S.C. § 337(a) impliedly preempts any state-law claim for which the violation of a federal regulation is a critical element.

Courts around the country have applied preemption in dismissing claims involving the design, manufacturing, and labeling/warnings for the SynchroMed® II Infusion System – often at the pleading stage. *See, e.g.*, *Ilarraza v. Medtronic, Inc.* 677 F. Supp. 2d 582, 586-90 (E.D.N.Y. 2009) (dismissing claims involving a SynchroMed® pump at the pleading stage); *McBride*, 2013 WL 3491085, at *3-5 (same); *Cenac v. Hubbell*, No. 09-3686, 2010 WL 4174573, at *3-7 (E.D. La., Oct. 21, 2010) (same); *see also Walker v. Medtronic, Inc.* 670 F.3d 569, 576-81 (4th Cir. 2012) (granting summary judgment).

Courts have reached the same result in cases involving other PMA medical devices, many of which were decided within the past year. *See, e.g.*, *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1337-47 (10th Cir. 2015), cert. denied, 2016 WL

100378 (U.S. Jan. 11, 2016) (No. 15-321); *Otis-Wisher v. Medtronic, Inc.*, 616 Fed. App'x. 433, 434-35 (2d Cir. 2015); *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 707 (S.D. Tex. 2014); *Zaccarello v. Medtronic, Inc.*, 38 F. Supp. 3d 1061, 1066-70 (W.D. Mo. 2014); *Martin v. Medtronic, Inc.*, 32 F. Supp. 3d 1026, 1040-45 (D. Ariz. 2014); *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1040-41 (D. Haw. 2014). Further, California courts have applied express and/or implied preemption in dismissing claims like Plaintiff's. *E.g.*, *Anderson v. Medtronic, Inc.*, No. 14-cv-00615-BAS(RBB), 2015 WL 2115342, at *6-9 (S.D. Cal. May 6, 2015); *Johnson v. Hologic, Inc.*, No. 2:14-cv-0794-JAM-KJN-PS, 2015 WL 75240, at *3-5 (E.D. Cal. Jan. 6, 2015); *Eidson v. Medtronic, Inc.*, 981 F. Supp. 2d 868, 883-92 (N.D. Cal. 2013); *Kashani-Matts v. Medtronic, Inc.*, No. SACV 13-01161-CJC(RNBx), 2013 WL 6147032, at *3-6 (C.D. Cal. Nov. 22, 2013); *Simmons v. Boston Scientific Corp.*, No. CV 12-7962 PA (FFMx), 2013 WL 1207421, at *2-6 (C.D. Cal. Mar. 25, 2013); *Norton v. Independence Tech., LLC*, No. 2:10-cv-03218-MCE-JFM, 2011 WL 3584491, at *2-3 (E.D. Cal. Aug. 15, 2011); *Erickson*, 846 F. Supp. 2d at 1090-94; *Cohen v. Guidant Corp.*, No. CV-05-8070-R, 2011 WL 637472, at *1-2 (C.D. Cal. Feb. 15, 2011); *McGuan v. Endovascular Techs., Inc.*, 182 Cal. App. 4th 974, 981-87 (2010); *Meaunrit v. The Pinnacle Foods Grp.*, No. C 09-04555 CW, 2010 WL 1838715, at *7 (N.D. Cal. May 5, 2010); *Prudhel v. Endologix, Inc.*, No. CIV. S-09-0661 LKK/KJM, 2009 WL 2045559, at *3-9 (E.D. Cal. July 9, 2009); *Jessen v. Mentor Corp*. 158 Cal. App. 4th 1480, 1489-92 (2008).

I. Plaintiff's Claims against Medtronic Are Expressly Preempted by Federal Law.

This Court must conduct a two-step process to determine whether Plaintiff's claims are expressly preempted under § 360k(a). *Riegel*, 552 U.S. at 321-22. ***First***, the Court must "determine whether the Federal Government has established requirements applicable to" the medical device at issue. *Id*. at 321. ***Second***, if so, the Court then must determine whether Plaintiff's claims "are based upon [state

law] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." *Id.* at 322 (citing § 360k(a)). When, as here, these two conditions are met, preemption applies.

A. Step 1: The SynchroMed® II Infusion System is Subject to Federal Requirements.

The first step of the express-preemption test articulated in *Riegel* is indisputably satisfied. As discussed above, the SynchroMed® Infusion System received premarket approval in 1988, and the FDA has since approved its components – including Plaintiff's Model 8637 pump and Model 8709SC catheter – through more than 200 PMA supplements. (FAC ¶¶ 13, 55 & Exs. A - E.)

In *Riegel*, the Supreme Court held that "[p]remarket approval … imposes [federal] 'requirements'" as that term is used in § 360k(a). 552 U.S. at 322. Accordingly, PMA devices like the SynchroMed® II Infusion System, including the Model 8709SC catheter, "automatically satisfy the first prong of the *Riegel* test." *McClelland v. Medtronic. Inc.*, 944 F. Supp. 2d 1193, 1199 (M.D. Fla. 2013). Further, "[p]remarket approval imposes federal requirements on the . . . device as a whole as well as each of its component parts." *Hawkins v. Medtronic, Inc.*, No. 1:13-CV-00499 AWI SKO, 2014 WL 346622, at *6 (E.D. Cal., Jan. 30, 2014). Thus, the federal government has established requirements for Plaintiff's device.

B. Step 2: Plaintiff's Claims Are Based on State Law That Is Different From, Or Additional To, Federal Law.

The second step of the *Riegel* express-preemption test is also satisfied. It is well settled under the Medical Device Amendments that state common-law and statutory "duties underlying negligence, strict-liability, and implied-warranty claims" are considered "requirements . . . 'with respect to devices.'" *Riegel*, 552 U.S. at 327. Further, as shown below, Plaintiff's claims would impose standards for device safety and effectiveness that are different from or additional to those set

by the FDA. This is despite Plaintiff's efforts to plead a "parallel" claim based on purported violations of FDA requirements.[5]

Turning to the Complaint, Counts 1 through 4 assert claims against Medtronic sounding in strict liability, negligence, and breach of warranty. The gravamen of each claim is that the SynchroMed® II Infusion System was not safe and effective as a result of Medtronic's purported failure to follow Current Good Manufacturing Practices ("CGMPs") in manufacturing the device.[6] (FAC ¶¶ 98-100, 113, 115-16, 124, 131.) Count 6 further alleges that Medtronic breached a purported duty to instruct and train device representatives and medical providers. (*Id*. ¶¶ 146-48). Counts 5, 7, and 8 allege that Medtronic made misrepresentations or omissions concerning the SynchroMed® II Infusion System's safety and efficacy. (*Id*. ¶¶ 135, 139-41, 151-53, 164, 171-72, 180-81.)

Plaintiff's claims are expressly preempted because they seek to impose obligations upon Medtronic beyond what federal law requires. Plaintiff does not allege that Medtronic deviated from any specific manufacturing or labeling requirement imposed by the FDA through the PMA process, but instead relies principally on Medtronic's alleged failure to follow CGMPs. As discussed in detail in Part I(C) below, alleged CGMP violations do not establish a parallel claim that

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[5] "'*Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).'" *Bryant v. Medtronic, Inc.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). Part I(C) addresses Plaintiff's failure to allege a valid parallel claim.

[6] Plaintiff does allege, in conclusory fashion, that her device "failed to . . . conform to the specifications approved by the FDA." (*E.g.*, FAC ¶ 103.) Plaintiff does not allege any facts suggesting which specifications were purportedly violated. Absent such facts, any claim based on this allegation is inadequately pled because the Court cannot "infer more than the mere possibility of misconduct." *Iqbal*, 556 U.S. at 679; *see infra* Part III.

can avoid express preemption. Moreover, Plaintiff seeks to impose duties on Medtronic beyond what the PMA requires, including "duties to train medical providers" to use the device. (FAC ¶ 146.) Such claims "disrupt[] the federal scheme" for regulating PMA medical devices by imposing additional obligations on manufacturers and thereby requiring such devices "to be safer, but hence less effective, than the model the FDA has approved." *Riegel*, 552 U.S. at 325.

Any claim based on a state-law requirement that Medtronic employ a different design, use a different manufacturing process, or provide different or additional warnings runs headlong into § 360k(a). As the Supreme Court has explained, § 360k(a) "[s]urely . . . would pre-empt a jury determination that the FDA-approved labeling for a [device] violated a state common-law requirement for additional warnings." *Riegel*, 552 U.S. at 329. As noted above, courts across the country agree and "have applied Section 360k(a) broadly, preempting all manner of claims from strict products liability and negligence, to breach of warranty, to failure to warn and manufacturing-and-design-defect, to negligence per se."[7] *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009) (citations omitted). As this case law establishes, Plaintiff's claims against Medtronic are expressly preempted by § 360k(a).

C. Plaintiff's Efforts to Plead a Parallel Claim Do Not Enable Her to Avoid Express Preemption.

As noted above, there is a narrow exception to express preemption under Section 360k(a) for claims that "'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330. But Plaintiff "cannot simply incant the

[7] Some courts have held that claims based on affirmative misrepresentations escape express preemption. *E.g.*, *Schouest*, 13 F. Supp. 3d at 703-04. As discussed in Parts III and IV below, however, Plaintiff's misrepresentation-based claims fail regardless of preemption because they are inadequately pled and barred on state-law grounds.

magic words '[defendant] violated FDA regulations' in order to avoid preemption." *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011). Nor is it enough for Plaintiff to base her claims on a violation of federal law. Rather, to be "parallel," a claim must rest on the violation of a state-law requirement that is "identical" to an existing federal requirement. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996); *accord Otis-Wisher*, 616 Fed. App'x at 434 ("The Supreme Court instructs that a state law claim must be 'identical' to an existing federal requirement" to avoid preemption); *see also Wolicki-Gables*, 634 F.3d at 1300 (to be parallel, requirements must be "'genuinely equivalent'"); *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005) (same).

Establishing liability via a parallel claim is thus "more difficult than it would be in a typical product liability case." *White v. Stryker Corp.*, 818 F. Supp. 2d 1032, 1037 (W.D. Ky. 2011). "To state a 'parallel' claim, a plaintiff must allege (1) the violation of a specific federal requirement applicable to the device; (2) the violation of an identical state-law duty; and (3) that the predicate federal violation caused his or her injuries." *Millman v. Medtronic*, No. 14-cv-1465, 2015 WL 778779, at *4 n.2 (D.N.J. 2015) (emphasis added); *accord, e.g.*, *Wolicki-Gables*, 634 F.3d at 1300–01; *McMullen*, 421 F.3d at 488–89; *Caplinger v. Medtronic, Inc.*, 921 F. Supp. 2d 1206, 1214 (W.D. Okla. 2013).

Here, Plaintiff seeks to avoid express preemption by pleading a laundry list of purported regulatory violations and citing FDA inspection notices, warning letters, and recalls of certain system components. (*See* FAC ¶¶ 25, 27, 56-89.) For two reasons, these allegations fail to state a parallel claim and avoid preemption.

i. Plaintiff alleges no violation of specific federal requirements.

First, an alleged CGMP violation cannot support a parallel claim that escapes express preemption. Although there is some division on this issue, which the Ninth Circuit has yet to address, courts around the country have held that a CGMP

violation "cannot serve as the basis for a parallel claim" that avoids preemption. *Ilarraza*, 677 F. Supp. 2d at 588.

CGMPs typically set forth open-ended standards, not concrete requirements; they are "intentionally vague and open-ended" and "open to a particular manufacturer's interpretation."[8] *Id*. Because of that flexibility and the concomitant discretion afforded manufacturers, state-law claims predicated on a plaintiff's particular interpretation of the CGMPs would necessarily be enforcing requirements "different from, or in addition to" any actual requirements that exist under federal law, and are therefore expressly preempted by § 360k(a). *See, e.g.*, *Pearsall v. Medtronics, Inc.*, No. CV 14-3378, 2015 WL 8160888, at *7 (E.D.N.Y. Dec. 7, 2015) ("The CGMPs are guidelines that do not create a federal requirement, and a claim based on alleged failure to comply with the guidelines fails to plead violation of a federal requirement"); *Burkett v. Smith & Nephew GmbH*, No. CV 12-4895 (LDW) (ARL), 2014 WL 1315315, at *5 (E.D.N.Y. Mar. 31, 2014) (manufacturing defect claim based on CGMPs was barred by preemption); *Horn v. Boston Sci. Neuromodulation Corp.*, No. CV409-074, 2011 WL 3893812, at *9 (S.D. Ga. Aug. 26, 2011) ("[B]ecause [CGMPs] fail to provide any tangible or concrete standard, this Court agrees that to allow a violation of such a flexible standard to result in

[8] The FDA has explained that, in contrast to a device's PMA (which details how a device must be manufactured), a CGMP "does not prescribe in detail how a manufacturer must produce a specific device," but rather gives manufacturers discretion "to determine the necessity for . . . some quality elements," and also "to develop and implement specific procedures tailored to their particular processes and devices." FDA, *Quality System (QS) Regulation/Medical Device Good Manufacturing Practices*, available at http://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/qualitysystemsregulations/default.htm#flexibility. Indeed, when the FDA adopted the CGMP regulation, the final rule that the agency ultimately promulgated had been revised to "provide manufacturers with even greater flexibility in achieving the quality requirements" than was initially proposed. *Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation*, 61 Fed. Reg. 52,602, 52,603 (Oct. 7, 1996).

liability would, in itself, be imposing a standard 'different from, or in addition to' those imposed by the [Medical Device Amendments].") (quoting 21 U.S.C. § 360k(a)(1)); *In re Medtronic*, 592 F. Supp. 2d at 1158 ("The flexibility inherent in the CGMPs . . . demonstrates why Plaintiffs' manufacturing-defect claims are not 'parallel.'"). *But see, e.g.*, *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 435-36 (2014) (allowing CGMP-based claim to proceed past the pleading stage); *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 158-59 (S.D.N.Y. 2011) (same).

Allowing Plaintiff to evade express preemption via reliance upon CGMPs – especially where she has not alleged a causal link to her injuries, as discussed below – would be contrary to *Riegel*. The purpose of a federal statute preempting state laws imposing differing requirements (§ 360k(a)) is frustrated if Plaintiff can bypass preemption by relying on flexible CGMPs – which are subject to *ad hoc* jury interpretations – rather than concrete PMA requirements.

ii. Plaintiff has not alleged a causal connection between a pertinent federal violation and her purported injuries.

Second, Plaintiff fails to allege facts plausibly suggesting that any purported violation of the CGMP regulations is causally connected to her alleged injuries. That is a fatal flaw, because to plead a "parallel claim[] that survive[s] preemption," Plaintiff must "allege facts . . . establishing a causal nexus between the alleged injury and the [alleged federal] violation." *Erickson*, 846 F. Supp. 2d at 1092 (quotation marks omitted); *accord, e.g.*, *Millman*, 2015 WL 778779, at *4 n.2; *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1174 (C.D. Cal. 2013). Thus, Plaintiff must allege a federal violation that (1) **caused** a manufacturing defect that, in turn, (2) **caused** her alleged injuries.

Plaintiff has not alleged facts plausibly establishing either – let alone each – link in this causal chain. She asserts that she experienced the known and warned-of complication of catheter fracture (*id.* ¶ 24), but she alleges no facts plausibly suggesting that the alleged fracture resulted from a manufacturing defect, let alone a

manufacturing defect caused by a CGMP violation. *E.g.*, *Rankin v. Boston Sci. Corp.*, No. 09-177-KSF, 2010 WL 672135, at *4 (E.D. Ky. Feb. 19, 2010) (plaintiff cannot avoid preemption based on "[t]he fact that the [device] allegedly failed during normal use"). Nor does she provide any factual backing for her claim that her pump (as opposed to the catheter itself) "malfunction[ed]." (*Id.* ¶ 24.) Instead, she lists a series of FDA actions purportedly showing that the SynchroMed® II Infusion System was defective. (*Id.* ¶¶ 25, 27, 56-89.) But these actions occurred years after Plaintiff's implant surgery, involved different device components, or otherwise have no alleged link to her alleged injuries, as shown below:

Alleged Federal Action[9]	**Source in Pleadings**	**Alleged Relation to Plaintiff's Device and Purported Injuries**
August 29, 2006 FDA Warning Letter (*see* FAC Ex. 1)	FAC ¶¶ 56-57, 59-60	No alleged causal relation. Dealt largely with the Model 8731 catheter (not alleged to be at issue here). No factual allegation that any purported violations in or before 2006 affected Plaintiff's device implanted in 2009.
July 3, 2007 FDA Warning Letter (*see* FAC Ex. 2)	FAC ¶¶ 58-60	No alleged causal relation. Dealt largely with FDA reporting and complaint handling procedures. No factual allegation that a 2007 failure to report affected Plaintiff's physician's 2009 decision to implant the device.
March 2008 Recall of SynchroMed® II Pumps (*see* Ex. F)	FAC ¶ 79	No alleged causal relation. Involved updates to labeling regarding inflammatory mass formation at the distal catheter tip – a topic not alleged to be at issue here.

[9] The documents cited in this chart are attached to and/or referenced in Plaintiff's Complaint and are central to her claims, and their authenticity is not subject to reasonable dispute. Therefore, they may be considered as part of the pleadings at the Rule 12(b)(6) stage. *Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998 (9th Cir. 2010). Many of the documents are also publically-available FDA records that are subject to judicial notice for the reasons applicable to Medtronic's PMA documentation. *See supra* at 3-5 & nn. 2-3.

June 1, 2009 FDA Warning Letter (*see* FAC Ex. 3)	FAC ¶¶ 61-65	No alleged causal relation. No factual allegation that the manufacturing and event reporting issues addressed in this letter affected Plaintiff's particular device or her physician's decision to implant the device.
February 2011 Recall of SynchroMed® II Pumps (*see* Ex. G)	FAC ¶ 78	No alleged causal relation. Issued 2 years after Plaintiff's implant surgery and involved guidance about unintended injection of medication into subcutaneous tissue at the pump pocket site during refill – a situation not alleged in Plaintiff's Complaint.
August 2011 Recall of SynchroMed® II Pumps (*see* Ex. H)	FAC ¶¶ 25, 77	No alleged causal relation. Issued over 2 years after Plaintiff's implant surgery and involved informational updates concerning potentially reduced battery performance in a small number of SynchroMed® II pumps, an issue first communicated to physicians in July 2009. No factual allegation that Plaintiff's pump exhibited a battery alarm or similar issue.
July 17, 2012 FDA Warning Letter (*see* FAC Ex. 4)	FAC ¶¶ 66-69	No alleged causal relation. Issued over 3 years after Plaintiff's implant surgery and involved complaint handling and corrective and preventative action issues. No factual allegation suggesting that the alleged issues affected Plaintiff's particular device, caused her device to allegedly fail, and/or affected her physician's decision to implant the device.
April 3, 2013 FDA Form 483 Letter (*see* FAC Ex. 5)	FAC ¶¶ 70-71	No alleged causal relation. Issued over 4 years after Plaintiff's implant surgery and principally involved the distribution of catheters between September 2012 and March 2013 following a redesign intended to reduce the potential for occlusion at the catheter-to-pump interface. No factual allegation that Plaintiff's injuries were causally related to occlusion at the catheter-to-pump interface.

May 2013 Device Removal Notice (*see* Ex. I)	FAC ¶ 27	No alleged causal relation. Issued over 4 years after Plaintiff's implant surgery and involved Medtronic's recall of unused catheters in response to the FDA's April 2013 Form 483 letter (*see supra*). No factual allegation that Plaintiff's injuries were causally related to occlusion at the catheter-to-pump interface.
June 2013 Recalls of SynchroMed® II Pumps (*see* Ex. J)	FAC ¶ 76	No alleged causal relation. Involved new guidance concerning priming bolus procedures and the potential for electrical shorting in certain pumps. No factual allegation that Plaintiff's injuries were causally related to a priming bolus or electrical short.
June 2013 Recall of Unused Catheters (*see* Ex. K)	FAC ¶ 75	No alleged causal relation. Issued over 4 years after Plaintiff's implant surgery and involved Medtronic's recall of unused catheters in response to the FDA's April 2013 Form 483 letter (*see supra*). No factual allegation that Plaintiff's injuries were causally related to occlusion at the catheter-to-pump interface.
April 2015 Consent Decree with FDA (*see* FAC Exs. 6-7)	FAC ¶¶ 80-89	No relation. Entered over 6 years after Plaintiff's implant surgery. No factual allegation causally linking the consent decree to any alleged malfunction, or to Plaintiff's alleged injuries.

As demonstrated above, Plaintiff has merely cited a host of FDA actions without alleging facts plausibly linking them to the specific SynchroMed® II pump and catheter implanted in her body in February 2009, let alone plausibly linking them to her alleged injuries. Moreover, the warning letters cited by Plaintiff do not constitute final agency findings of federal violations, nor would any alleged recalls affect the validity of the premarket approval for the SynchroMed® II Infusion System. *See, e.g.*, *Cody Labs., Inc. v. Sebelius*, 446 F. App'x. 964, 969 (10th Cir.

2011) ("every court to consider the question has held that an FDA warning letter does not constitute 'final agency action'"); *see also In re Medtronic*, 592 F. Supp. 2d at 1155-56 (rejecting argument that preemption did not apply in light of a Class I recall, noting that recalls do not invalidate a device's PMA, and distinguishing between PMA revocation and recalls).[10]

Courts regularly dismiss complaints, like Plaintiff's, that list purported regulatory violations without linking them to specific alleged malfunctions and injuries. *Simmons*, 2013 WL 1207421, at *4 ("Plaintiff fails to link the recalls or advisories to the malfunction at issue here in any more than a conclusory manner"); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 283 (E.D.N.Y. 2009) (dismissing where plaintiff "failed to demonstrate that the injuries she sustained resulted from the violations spelled out in the warning letters"); *Prudhel*, 2009 WL 2045559, at *8 ("Although plaintiffs[] generally allege that many violations of federal requirements occur, to state a parallel claim, a federal violation must be a predicate to the theory of liability.") (emphasis added). As in these cases, Plaintiff has not alleged facts plausibly linking her particular device or injuries to a violation of a specific federal requirement for the SynchroMed® II Infusion System.

II. Plaintiff's Claims Are Impliedly Preempted By Federal Law.

Even if 21 U.S.C. § 360k(a) did not expressly preempt CGMP-based claims, and even if the Complaint adequately alleged a causal link between a purported regulatory violation and Plaintiff's injuries, her claims would still fall to implied preemption, as applied in *Buckman*.[11]

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[10] PMA revocation is governed by a detailed statutory and regulatory procedure requiring explicit FDA action. *See, e.g.*, 21 U.S.C. § 360e(e), (g); 21 C.F.R. §§ 10.45, 16.62, 16.80, 16.95, 16.120, 814.46. The FDA has never revoked the SynchroMed® II Infusion System's PMA status.

[11] The mere fact that a claim might avoid express preemption under § 360k(a) has no bearing on implied preemption, because "neither an express pre-emption provision nor

In enacting the FDCA, Congress not only declined to create a private cause of action, but affirmatively required that any action to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). This statute mandates that the FDCA and its implementing regulations be "enforced exclusively by the Federal Government." *Buckman*, 531 U.S. at 352. Moreover, Congress granted the FDA "complete discretion" in deciding "how and when [its enforcement tools] should be exercised." *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). That discretion is necessary "to achieve a somewhat delicate balance of statutory objectives," a balance that "can be skewed" if private tort suits are allowed. *Buckman*, 531 U.S. at 348. "This flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives." *Id.* at 349. Thus, "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Id.* at 349 n.4.

Through § 337(a), Congress impliedly preempted any private action seeking to enforce the FDCA and its implementing regulations. Accordingly, any claim that relies on the FDCA or its regulations "'[a]s a critical element'" is barred by § 337(a). *Marsh v. Genentech, Inc.*, 693 F.3d 546, 553 (6th Cir. 2012) (quoting *Buckman*, 531 U.S. at 353). That the claim might be styled a state-law claim is immaterial: "'a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA.'" *Leonard v. Medtronic, Inc.*, No. 1:10-CV-03787-JEC, 2011 WL 3652311, at *7 (N.D. Ga. 2011) (quoting *Riley*, 625 F. Supp. 2d at 777); *accord*, *e.g.*, *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 856 (W.D. Tenn. 2015) ("A

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a saving clause 'bar[s] the ordinary working of conflict preemption principles.'" *Buckman*, 531 U.S. at 352 (quoting *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000)).

plaintiff cannot bring a state-law claim that is in substance a claim to enforce the FDCA."). In short, "Plaintiff[] cannot make an end run around [§ 337(a)] by recasting violations of the FDCA as violations of state common law."[12] *In re Medtronic*, 592 F. Supp. 2d at 1161.

Plaintiff repeatedly alleges that her device was "adulterated" and "misbranded" under the FDCA due to purported CGMP violations. (FAC ¶¶ 58, 59, 61, 64, 66, 98, 113, 114, 124, 131, 164, 171, 181.) Given § 337(a), however, state-law claims "are not saved merely by being recast as violations of the federal adulteration and misbranding statutes." *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008). Indeed, any argument that Plaintiff's "claims are not preempted because the [device] was 'adulterated'" or misbranded "must fail," because "violations of the FDCA do not create private rights of action" and "only the government has a right to take action with respect to adulterated [or misbranded] products." *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir. 1994); *accord, e.g.*, *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 659-60 (S.D. Tex. 2010) (claims seeking to enforce federal law concerning "adulterated" devices impliedly preempted). Because only the federal government can enforce the FDCA and its regulations, claims based on alleged violations of the CGMP regulations conflict with the FDA's regulatory regime. This Court should follow *Buckman* and its progeny and hold that Plaintiff's claims are impliedly preempted.

[12] The Ninth Circuit has held that, under Arizona law, a failure-to-warn claim based on an alleged failure to report adverse events to the FDA may survive implied (as well as express) preemption. *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013). However, such claims face unique causation hurdles. *Id.* at 1234 (Watford, J., concurring) ("To prevail, [plaintiffs] will ultimately have to prove that if Medtronic had properly reported the adverse events to the FDA as required under federal law, that information would have reached Mr. Stengel's doctors in time to prevent his injuries."); *Martin*, 32 F. Supp. 3d at 1043 (dismissing failure-to-report claim based on inadequate causation allegations). Plaintiff's failure-to-warn claim is preempted because she does not allege a causal link between any reporting failure and her injuries. *See* Parts I(C)(iii) & III.

III. Plaintiff's Claims Are Inadequately Pleaded.

Even if her claims were not preempted, Plaintiff's Complaint should be dismissed for failure to satisfy federal pleading standards. Principally, the Complaint contains no factual allegations plausibly showing a product defect or causation. As discussed above in Part I(C), the Complaint describes years of FDA oversight of Medtronic's manufacturing and reporting processes. (FAC ¶¶ 25, 27, 56-89.) But Plaintiff alleges no facts linking these issues to her catheter's purported breakage or to an unspecified pump malfunction. Nor does the Complaint suggest that any purported federal violations occurred before her February 2009 implant surgery, actually affected her device, and impacted her physician's decision to implant the device. Absent such allegations, this Court cannot "infer more than the mere possibility of misconduct." *Iqbal*, 556 U.S. at 679.

Moreover, despite pleading claims sounding in fraud in Counts 5, 7, and 8, Plaintiff has not come close to providing the factual specificity required by Rule 9(b). To comply with the rule, "a plaintiff must plead with particularity the time and place of the fraud, the statements made and by whom made, an explanation of why or how such statements were false or misleading when made, and the role of each defendant in the alleged fraud." *Erickson*, 846 F. Supp. 2d at 1090 (quotation marks omitted). The allegations "must be specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." *Kashani-Matts*, 2013 WL 6147032, at *2 (quotation marks omitted).

Plaintiff's Complaint fails to identify the date or circumstances of any representations made directly to Plaintiff or her physicians. (*See, e.g.*, FAC ¶ 21 (alleging that, "at times," unspecified Medtronic representatives "would appear in her physician's office" to generally explain the benefits of the SynchroMed® II Infusion System). She instead merely asserts that "Medtronic" made general representations regarding the SynchroMed® II Infusion System in brochures (*id.* ¶

135), or engaged in unspecified "fraudulent business practices" (*id*. ¶ 153), or made "false and misleading" statements concerning the device (*id*. ¶ 165), without identifying the particular statements that were allegedly false or when they were made. These allegations fall well short of what Rule 9(b) requires.

Finally, Plaintiff's Complaint provides scant facts regarding the content of any warranty Medtronic made specifically to her and upon which she relied, or when or how any such warranty was made. Instead, Plaintiff merely alleges that Medtronic "expressly warranted by way of written literature" that the SynchroMed® II Infusion System was safe and effective. (FAC ¶ 123.) Such allegations are insufficient to state a plausible claim for breach of warranty.[13] *Dunbar v. Medtronic, Inc*., No. CV 14-01529-RGK (AJWXx), 2014 WL 3056026, at *8 (C.D. Cal. June 25, 2014) (dismissing warranty claim where plaintiffs did not allege "that Medtronic made any affirmations specifically to Plaintiffs or their surgeons, so as to form the basis of the bargain"). In short, the Complaint fails to provide adequate notice of the basis for Plaintiff's claims.

IV. Plaintiff's Claims Are Barred on Independent State-Law Grounds.

Preemption and pleading standards aside, Plaintiff's claims fail under California law for several reasons.

A. Plaintiff's Claims Are Barred by the Statute of Limitations.

Plaintiff's device was implanted in February 2009, and her alleged injuries manifested "shortly" thereafter. (FAC ¶¶ 20-21.) Further, in December 2011, Plaintiff's physicians allegedly determined that "medication was not being delivered to her intrathecal space" due to a device malfunction. (*Id.* ¶ 22.) Despite

[13] Plaintiff's implied-warranty claim in Count 4 fails for the additional reason that she did not (and cannot) allege that she is in privity of contract with Medtronic with respect to the sale of the SynchroMed® II Infusion System. *Coleman v. Boston Scientific Corp*., No. 1:10-cv-01968-OWW-SKO, 2011 WL 1532477, at *6 (E.D. Cal. Apr. 20, 2011) (dismissing implied-warranty claim with prejudice based on lack of privity).

this, Plaintiff did not file her original Complaint until April 2015 – more than six years after her complications allegedly began. Given these facts, Plaintiff's claims are barred by California's two-year statute of limitations for personal injury claims, even with the benefit of the discovery rule.

In this federal diversity action brought under California law, the California statute of limitations governs. *Eidson*, 981 F. Supp. 2d at 892. California applies a two-year statute of limitations to all personal injury claims based upon defective products, regardless of the legal theory invoked. *Id.* at 893; Cal. Code Civ. P. § 335.1. A cause of action for personal injury generally accrues on the date of injury, but the discovery rule may delay accrual until Plaintiff "suspects or should suspect that [her] injury was caused by wrongdoing, that someone has done something wrong to [her]." *Jolly v. Eli Lilly & Co.*, 44 Cal. 3d 1103, 1110 (1988). This standard requires only "a suspicion of wrongdoing," not knowledge of "the specific 'facts' necessary to establish the claim." *Id.* at 1111 (emphasis added). Thus, "[a] plaintiff whose complaint shows on its face that [her] claim would be barred without the benefit of the discovery rule must specifically plead facts to show (1) the time and manner of discovery and (2) the inability to have made earlier discovery despite reasonable diligence." *Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal. 4th 797, 808 (2005) (quotation marks omitted, emphasis in original).

Because Plaintiff alleges that her injuries began in February 2009 and continued for years, her claim is facially time-barred without the benefit of the discovery rule. But even with the rule's benefit, Plaintiff fares no better. She affirmatively alleges that in December 2011, her physician "believ[ed] the medication was not being delivered to her intrathecal space" and therefore performed revision surgery "to replace the malfunctioning SynchroMed® II System." (FAC ¶ 22.) Thus, Plaintiff admits she had notice of a potential problem with her device no later than December 2011 – more than three years before she filed this lawsuit. Plaintiff does not "specifically plead facts" showing that her

injury was not discoverable earlier than April 2013, two years before her Complaint was filed. *Fox*, 35 Cal. 4th at 808. To the contrary, her allegations confirm that she had notice of a possible defect in 2011, but did not take action for nearly four years. Thus, Plaintiff's claims are time-barred and should be dismissed.

B. Plaintiff's UCL Claim Is Barred under California Law.

California's UCL "defines unfair competition to include any 'unlawful, unfair or fraudulent business act or practice.' Each of these three prongs—unlawful, unfair, or fraudulent—implicates a different legal standard." *Davis-Miller v. Auto. Club of S. Cal.*, 201 Cal. App. 4th 106, 111 n.2 (2011) (quoting Cal. Bus. & Prof. Code § 17200). Plaintiff's UCL claim proceeds under two of the three prongs: she alleges that Medtronic (1) committed "acts of unfair competition" by "falsely advertising" the SynchroMed® II Infusion System and "intentionally concealing" its risks (FAC ¶ 151), and (2) engaged in "fraudulent business practices" (*id.* ¶ 153). For two reasons, this claim must be dismissed.

First, Medtronic's compliance with FDA labeling requirements precludes UCL liability. The California Supreme Court has stated that "[i]f the Legislature has permitted certain conduct or considered a situation and concluded no action should lie, courts may not override that determination." *Cel-Tech Commc'ns, Inc. v. L.A. Cellular Tel. Co.*, 20 Cal. 4th 163, 182 (1999). The Ninth Circuit has extended this safe-harbor rule to claims involving federal statutes and regulations. *Davis v. HSBC Bank Nev., N.A.*, 691 F.3d 1152, 1165-66 (9th Cir. 2012).

As discussed above, the FDA exercises rigorous oversight of the labeling and sale of the SynchroMed® II Infusion System. Plaintiff alleges no facts suggesting that Medtronic's labeling for the device was contrary to the PMA specifications, and her Complaint provides little factual detail to support her conclusory allegations of fraud, false advertising, and risk concealment. (FAC ¶¶ 151, 153.) Therefore, Plaintiff has not stated a UCL claim against Medtronic. *See, e.g.*, *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, No. 13–11343–NMG, 2014 WL 866571, at

*4-5 (D. Mass. Mar. 5, 2014) (dismissing California UCL claim against drug manufacturer), *aff'd on other grounds*, 779 F.3d 34 (1st Cir. 2015); *Pom Wonderful LLC v. Coca Cola Co.*, No. CV 08-06237 SJO (FMOx), 2013 WL 543361, at *5 (C.D. Cal. Feb. 13, 2013) (defendant's compliance with FDA regulations warranted dismissal of UCL claim).

Second, the relief Plaintiff seeks on this claim is unavailable as a matter of law. In an individual action, "[t]he UCL limits the remedies available for UCL violations to restitution and injunctive relief." *Madrid v. Perot Sys. Corp.*, 130 Cal. App. 4th 440, 452 (2005). Thus, Plaintiff cannot obtain the money damages she seeks. (FAC ¶ 157); *Korea Supply Co. v. Lockheed Martin Corp.*, 29 Cal. 4th 1134, 1150 (2003) ("it is well established that individuals may not recover damages" under the UCL). The same is true of Plaintiff's request for disgorgement of Medtronic's earnings from selling the SynchroMed® II Infusion System. *Id.* at 1150-52; *Adams v. I-Flow Corp.*, No. CV09-09550 R(SSX), 2010 WL 1339948, at *7 (C.D. Cal. Mar. 30, 2010) (striking request for disgorgement of profits from sale of medical device); (FAC ¶ 155). Nor may Plaintiff obtain injunctive relief (*id.* ¶¶ 155-56), since (1) the damages she seeks on her other claims would adequately redress her alleged injuries, and (2) despite seeking relief on behalf of herself "and others similarly situated" (*id.* ¶ 156), Plaintiff has not even attempted to satisfy class-action pleading requirements, as is required to obtain such relief. *Rhynes v. Stryker Corp.*, No. 10-5619 SC, 2011 WL 2149095, at *4 (N.D. Cal. May 31, 2011); *Adams*, 2010 WL 1339948, at *7; Cal. Bus. & Prof. Code § 17203.

CONCLUSION

For the foregoing reasons, Medtronic respectfully requests that the Court grant this Motion, dismiss all of Plaintiff's purported causes of action against Medtronic with prejudice, and award Medtronic its costs and such other relief as the Court may deem appropriate.

Dated: February 8, 2016 **MEDTRONIC, INC.**

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CERTIFICATE OF SERVICE

I hereby certify that on February 8, 2016, I electronically filed the foregoing **NOTICE OF MOTION TO DISMISS** and **DEFENDANT MEDTRONIC, INC.'S RULE 12(b)(6) MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT** with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the following counsel of record:

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